Running title: Delphi Study of Analysis of Videofluoroscopic Studies of Swallowing

Visuoperceptual Analysis of the Videofluoroscopic Study of Swallowing: An International Delphi study

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Declaration of interest:

The authors have no competing interests to declare.

*The first author completed this study as part of the requirements for the completion of a PhD under supervision of Reinie Cordier, Ted Brown and Renée Speyer. The authors wish to acknowledge Curtin University and the Australian Federal Government for the Curtin University Postgraduate Scholarship (CUPS) and the Australian Postgraduate Award (APA).

Abstract

Introduction

The Videofluoroscopic Swallow Study (VFSS) is a commonly used dysphagia assessment that is routinely analysed visuoperceptually. However, no consensus exists regarding which visuoperceptual measures should be used to analyse VFSSs. Current visuoperceptual measures for VFSSs are limited by poor quality and incomplete or indeterminate psychometric properties.

Objective

This study aimed to establish the content validity for a new visuoperceptual VFSS measure for oropharyngeal dysphagia in adults, by identifying relevant domains of the construct and generating items and corresponding response scales.

Methods

Consensus among experts in dysphagia and VFSS from over 20 countries was achieved across three rounds of anonymous online surveys, using the Delphi technique. Participants judged relevance and comprehensiveness of definitions of visuoperceptual domains of VFSS and the relevance of various domains to the overall construct. After reaching consensus on definitions of relevant domains, consensus on items were established using the same process.

Results

Participants achieved consensus on definitions of 32 domains recommended for analysis, and at least one item per domain (range: 1 – 4). Domains selected by participants included both those which occur in existing measures and domains which have not been included in any measures to date. This study will form the basis for content validity of a new measure for VFSS.

Conclusions

This first phase of developing a visuoperceptual measure of VFSS resulted in the identification of 32 domains and 60 items for oropharyngeal dysphagia. Developers can now advance to the next phase of measure construction; prototype development and psychometric testing.

Keywords: Videofluoroscopy, VFSS, modified barium swallow, deglutition, measure, content validity, instrument development.

Introduction

The videofluoroscopic swallow study (VFSS) and Fibre-Optic Endoscopic Evaluation of Swallowing (FEES) are widely acknowledged Gold-Standard instrumental assessments of dysphagia (Huckabee, Macrae, & Lamvik, 2015). The VFSS is a widely used instrumental assessment that provides direct viewing of the oral phase of the swallow, the cervical oesophagus and substructures related to swallowing (e.g., hyoid bone), and intra-swallow aspiration (Ciucci, Jones, Malandraki, & Hutcheson, 2016). However, the typical clinical analysis of VFSS, which involves subjective visuoperceptual examination recordings, is problematic as current measures exhibit poor validity and reliability (Lee, Randall, Evangelista, Kuhn, & Belafsky, 2017). Moreover, researchers have questioned whether visual perceptual measures for interpreting VFSS has adequate inter-rater reliability for routine clinical use (McCullough et al., 2001; Wilcox, Liss, & Siegel, 1996).

Commonly used measures for the visuoperceptual analysis and interpretation of VFSS include the Penetration-Aspiration Scale (Rosenbek, Robbins, Roecker, Coyle, & Wood, 1996) and MBS Measurement Tool for Swallow Impairment (MBSImp) (Martin-Harris et al., 2008). These, and other measures, were recently examined in a systematic review of the psychometric properties of visuoperceptual measures for VFSS and FEES (Swan, Cordier, Brown, & Speyer, 2018). This review identified nine visuoperceptual VFSS measures with evidence pertaining to validity and reliability (Swan et al., 2018). The measures were analysed according to the quality criteria for measurement properties from the COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN) guidelines (Mokkink et al., 2010; Terwee et al., 2007), an international consensus-based taxonomy with quality standards for psychometric properties. All of the visuoperceptual VFSS measures included in the review had poor, lacking or indeterminate psychometric properties. No measures were found to have sufficient psychometric evidence to support the recommendation for their clinical use. Similar issues were found with measures for FEES.

These results are of serious concern given the common use of VFSS in both research and clinical practice. When psychometric quality is inadequate or unclear, concerns may arise regarding clinical decisions that are made using information from the measure (Brown, 2009). This issue has been recognised in the field of VFSS, and a number of software based and more objective quantitative measures have been developed, such as the Analysis of Swallowing Physiology: Event, Kinematics and Timing (ASPEKT) method (Steele et al., 2019). However, such rigorous quantitative measurement is very time-consuming and, thus, costly, which limits its usability in clinical practice. As

such, there is a need for a psychometrically robust measure for visuoperceptual analysis of VFSS, that allows for expeditious interpretation of VFSS.

Content validity is, arguably, the most important psychometric property and reflects the degree to which the content of the measure is an adequate reflection of the underlying construct (Mokkink et al., 2018; Terwee et al., 2018). For a measure to have good content validity, it should have been developed using current literature and with reference to expert groups and (if appropriate) patient focus groups. It should comprehensively reflect the 'construct' of interest (the characteristic or trait to be measured). If content validity is flawed or lacking, the entirety of the measure is of questionable value.

Informed by the COSMIN guidelines, this manuscript reports on the results from a Delphi study aimed at developing content validity for a new visuoperceptual measure for VFSS. Existing visuoperceptual measures for VFSS are inconsistent with regards to:

1) the range of domains related to the construct included (i.e., the over-arching concept that is the target of the measure; e.g., pharyngeal constriction);

2) the range of items that compose the corresponding domains of the construct (e.g., oral transit time or volume of aspirated material); and

3) response scales that quantifies the observed items (e.g., a 5-point Likert scale; Swan et al., 2018).

In addition, definitions of domains across measure are often unclear or contradictory, and the construct of interest is poorly defined. Therefore, before a new measure can be created, content validity must be established by addressing the following research questions:

1) Which domains should be assessed in analysis VFSS of adults with oropharyngeal dysphagia?

2) Which definitions of these domains are widely accepted by experts?

3) How should these domains be operationalised and quantified as observable items?

In this study, oropharyngeal dysphagia referred to dysphagia which impairs the oral preparatory, oral and / pharyngeal swallow function (Rommel, 2016). Function of the upper oesophageal sphincter was included in this construct, as the swallow cannot be considered complete without opening of the sphincter (Steele et al., 2019).

Methods

Study Design

This study used the Delphi technique, which is an iterative process that establishes consensus through a series of structured questionnaires (Trevelyan & Robinson, 2015). Each version is modified, informed by feedback received in preceding rounds. Participants are experts in a specific topic area and remain anonymous from each other across rounds, therefore discouraging individuals from biasing the group, and encouraging sharing of diverse ideas. The Delphi technique is useful for generating new content, as it facilitates detailed communication about specific issues and identifies new or ideal practices, rather than merely reflecting the status quo (Hsu & Sandford, 2007; Kalaian & Kasim, 2012). In this study, the technique was used with on-line questionnaires ('e-Delphis') to build expert consensus regarding domains and items which should be included in a visuoperceptual measure of VFSS.

Participants

Eligibility Criteria

Eligibility criteria for participation in the Delphi Study included:

1) Self-identified as able to read English at an intermediate level (defined as able to understand the main points of texts pertaining to matters routinely encountered in clinical practice and understand English-language technical terms relevant to the field; e.g., anatomical terms).

2) Have worked with adults with dysphagia for more than five years (which may include provision of clinical services, where at least 50% of more of the caseload included adults with dysphagia; research activities relating to adults with dysphagia and/or staff development; academic teaching, and; resource development or consultancy where more than half of these activities pertain to adults with dysphagia).

3) Have spent an average of one hour per week engaged in activities related to VFSS over the past two years (activities included – used VFSS to analyse swallowing in a clinical caseload; conducted teaching relating to VFSS; developed resources relating to VFSS, and; been involved in research related to VFSS).

Procedure

Recruitment

The study was approved by the Human Research Ethics Committee [blinded for peer-review]. The following strategies were employed to recruit participants: 1) by identifying authors of research regarding VFSS and adults with dysphagia, 2) via professional organisations (e.g., European Society for Swallowing Disorders, Speech Pathology Australia Special interest groups and the Japanese Society of Dysphagia Rehabilitation) and, 3) from the professional networks of the researchers. Snowballing was also used (i.e., recruited participants were asked to identify other potential participants) (Flanagan, Ashmore, Banks & McInnes 2016). Once identified, participants were sent an email invitation and information sheet about the study. All participants who accepted the email invitation were included in the study. Any participants who did not respond to a survey round were excluded from subsequent rounds.

The study details were outlined at the beginning of each survey, with participants required to indicate consent to participate before accessing the remainder of the survey content. The final round provided participants with the option to consent for their names to be acknowledged in the publication of results.

The eDelphi

Domains for VFSS analysis were formulated initially from the dimensional composition of the VFSS measures included in the systematic review by Swan et al. (2018). Additional domains were then added from wider literature describing visuoperceptual VFSS analysis and based on the authors' clinical experience. Definitions for the domains were derived from the literature and reviewed by two authors (initials blinded for peer review). Although this study targeted oropharyngeal dysphagia, two oesophageal domains (Martin-Harris et al., 2008; Miles, 2016) were identified in a COSMIN review conducted by Swan et al. (2018) and were therefore included in the initial round, to determine suitability for inclusion in the construct. Domains were presented to participants across three rounds via an on-line survey platform (www.qualtrics.com), where participants indicated consensus on relevance, definitions and operationalisation with 5-point Likert scale responses (i.e., Strongly Disagree, Disagree, Neither Agree nor Disagree, Agree and Strongly Agree) (Trevelyan & Robinson,

2015). Participants who disagreed were asked to describe their suggested changes to definitions in open text boxes. Between rounds, responses were analysed to identify which domains met the consensus threshold (70% of respondents indicating agreement or strong agreement) for relevance and acceptance of definitions (Diamond et al., 2014; Hsu & Sandford, 2007; Miller, 2006).

Where definitions failed to meet consensus, adjustments were made both according to participant comments and the literature. Two authors reviewed these changes and reached consensus on if the change was minimal or substantial; if the definition change was substantial (defined as a major change to the meaning or wording of the definition), the variable and revised definition was re-presented in later rounds for evaluation. In rounds two and three participants were also asked to indicate preferences for the most appropriate way to 'operationalise' the domain; that is, defining the variables into measurable factors that could be measured empirically and by means of visual perceptual observation. Finally, an open-ended comment sections were available in all rounds.

On-line supplement: Structure and content of rounds

Round One

Survey Round One's content was structured as follows:

- A list of definitions of key psychometric terms;
- Demographic questions (qualifications, years of experience, caseloads and places of work);
- Domains of VFSS and definitions of domains, with Likert scale responses and text boxes for additional comments; and
- Open-ended text box for suggestions of additional domains.

Survey questions were divided into three parts; in the first, participants indicated their level of agreement with the definitions, in the second, the 'importance' of the domain. 'Important' was defined as the participant agreeing: 1) the domain adds significant information which is *relevant* to the VFSS analysis, such as assisting with diagnosis of underlying pathology, planning rehabilitation or assessing safety, and; 2) the domain should be *routinely incorporated* into VFSS analysis. Figure 1 provides an example of a Round One question.

Figure 1. Example round one question

Aspiration:

The bolus or a portion of the bolus passes level of the true vocal folds.

Q1. Do you agree with the definition for aspiration?

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

Q2. Rate the importance of the variable aspiration when analysing VFSS:

- Essential: Always assess
- Important: Assess in most situations
- Limited: Assess in some situations
- Irrelevant: Inappropriate to assess
- Unsure

Q3. Additional comments about aspiration:

_____

Round Two

In Round 2, participants were provided with a summary of Round One results followed by questions on:

- New domains of VFSS and definitions of domains formulated from Round One participant suggestions, with Likert scale responses and text boxes for additional comments;
- Domains presented in Round One which had met criteria for 'important', but had substantive changes to the definitions; and
- Operationalisation of Round One domains which had consensus/minimal changes of definitions and were considered 'important' (highly relevant).

Domains and definitions were presented for consensus as per the process in Round One, with Likert scale response options to statements, while operationalisation questions offered lists of items to measure the domain (Figure 2). The options for operationalisation were developed using the framework by Swan et al. (2018), where authors noted items used in visuoperceptual measures for VFSS fit into one of four categories: i) 'spatial' (items which described how the anatomical structure

or swallowed material moved in space; e.g., movement of the epiglottis), ii) 'temporal' (described the duration or time of onset of events; e.g., opening of the upper oesophageal sphincter), iii) 'patient response' (described variables where the patient reacted to an atypical event of the swallow; e.g., coughing in response to aspiration) or iv) 'volume' (amount of swallowed material present at a specific time; e.g., amount of residue present in valleculae post swallow).

Figure 2. Example of question regarding domain operationalisation (Round Two)

Aspiration:

The bolus or a portion of the bolus passes below the level of the true vocal folds.

ASPIRATION (max. 2 choices)

- □ Latency between material being aspirated and the patient response (e.g., time in ms)
- □ Depth of material when overt sign occurs (e.g. 5mm below the vocal folds) ,
- □ Volume of material present when patient response initiated (e.g. >10% of the bolus)
- □ Success in ejecting material from the airway (e.g. material not ejected from the airway)
- □ Other (_____)

Please select only two options. If other is selected, please suggest an alternative item.

Round Three

Round Three questions included:

- Options for operationalisation of Round Two domains which had consensus/minimal changes of definitions and were considered 'important' (highly relevant);
- Ranked options of the number of items each domain required to adequately capture each construct;
- One question clarifying the definition of 'delayed swallow';
- Four questions regarding the visuoperceptual quantification of specific concepts from Round Two operationalisation, for example, volume as pertains to aspirated material (Figure 3); and

- Eight questions regarding preferences for number of items required to adequately analyse domains from Round Two, where more than one variable met the threshold for consensus (Figure 4).

Figure 3. Example of question regarding quantification of items (Round Three)

Volume: aspirated material

In Round 2, participants selected 'Volume' as an appropriate measurement of aspiration and silent aspiration. Please indicate how volume of aspirated material should be quantified:

- □ Estimation of amount of total bolus aspirated (e.g., < 25%, 25 - 50%, 50 - 75%)
- □ Estimation of surface area in relation to marker of known diameter (e.g. depth of aspiration: < half size of marker, width of aspiration : < 1/4 size of marker)
- □ Estimation of cm2 in relation to marker of known diameter (e.g. depth of aspiration: 2cm, width of aspiration: < 0.5 cm)
- □ Estimation of volume below vocal folds using descriptors and / or pictorial references (e.g., none: no material visible, trace: line coating tracheal wall, more than trace: line coating tracheal wall and small amount of material visible in tracheal space etc)

□ Other:(_____)

If other is selected, please suggest an alternative operationalisation system.

Figure 4 – example of question regarding number of items required to assess an domain (Round Three)

Analysis of aspiration

Two items reached the threshold for consensus for inclusion in analysis of aspiration:

1. Time between material being aspirated silently and the initiation of the pharyngeal swallow (e.g., before / during / after)
2. Location of source of aspiration (e.g., oral cavity / valleculae residue / hypopharynx / pyriform sinus residue / reflux)

Should analysis of aspiration involve BOTH of these items?

- □ Yes
- □ No
- □ Other (e.g., 'only number 1') *comment:* _____

_____

With the exception of the variables ‘clearing swallow’, ‘penetration’, ‘aspiration’ and ‘silent aspiration’, participants were restricted to choosing a maximum of two items per domain. These domains were permitted more items as participants reached consensus in Round Three that all of the items selected in Round Two may be suitable.

Analysis

Survey responses from participants were analysed using a mixed methods approach, including both quantitative and qualitative data analysis (Tapio, Paloniemi, Varho, & Vinnari, 2011). Responses were imported into the Statistical Package for the Social Sciences (SPSS) software for analysis (IBM Corporation, 2015) to determine if consensus criterion was met, that is, 70% or more of experts selecting agree / strongly agree or essential / important on Likert Scale questions (i.e., a median score of one, indicating strong agreement, or two, indicating agreement, on a 5-point Likert scale and an IQR of one, indicating high levels of agreement) (Diamond et al., 2014; Hsu & Sandford, 2007; Miller, 2006).

Participant responses to open-ended questions were analysed with a mixed methods approach. Summative content analysis of Rounds One and Two was conducted, where comments were grouped according to similar suggestions regarding items or changes to definitions, and then aggregated to identify the changes recommended by respondents (Hsieh & Shannon, 2005). Where models or literature was suggested, the relevant evidence was retrieved and reviewed for applicability to this project and accepted according to consensus by two authors. Changes to definitions and the inclusion/exclusion of new domains and items were made in accordance with: a) the themes noted in the majority of comments, b) comments with supporting literature, and c) any comments which addressed gaps or ambiguity in the domains and definitions.

At least 70% of participants were required to select an item for it to meet the threshold for acceptance into Round Two. In Round Three, participants were able to indicate how many items were needed to rate each variable and then rank options for items. Where at least 70% of participants indicated that two variables were required, the two most highly ranked items were accepted. Where participants indicated only one variable was required, the item selected by the majority of participants was accepted. Finally, each comment in Round Three which suggested alteration or addition to items

or operationalisation was discussed between two authors for consensus on actionable changes. All analysis was conducted by the first author and reviewed by all co-authors.

Results

Participants

A total of 105 potential participants were identified through review of relevant publications and professional networks; 52 consented to take part. An additional nine participants were recruited via snow-balling. The demographics of the participants who completed each round are presented in the Table 1. Fifty-six participants took part in Round One (91%). Of these 56 participants, 42 completed Round Two (75%) while 34 completed Round Three (81%). Approximately half had qualifications in Speech-Language Pathology across all rounds (48 – 50%), with the remainder qualified in medicine, occupational therapy or dentistry. Among participants with qualifications in medicine, by the final round, the majority had qualifications in Radiology (n=6 / 38%), a quarter specialised in Rehabilitation medicine (n= 4) and 19% specialised in Otorhinolaryngology (n = 3). This pattern was similar across Rounds One and Two.

The majority of participants had completed higher degrees by research; in the final round, 64% had completed PhDs and 12% Master's degrees by research. Most participants had over 15 years of experience working with adults with dysphagia – 53% (n= 18) at Round Three. The majority of participants worked in Universities and / or the Health care sector (83%). The patient populations most participants worked with included neurology, oncology, sub-acute care (rehabilitation) and acute care (e.g. general medicine). Participants were spread across 27 countries in Round One, and 21 countries by Round Three.

Online supplementary Table 1: Participant demographics

	Round One		Round Two		Round Three	
	Frequency	**Percentage**	**Frequency**	**Percentage**	**Frequency**	**Percentage**
Participant profession	**N = 56**		**N = 42**		**N = 34**	
Speech Language Pathology	28	50	20	48	17	50
Medicine	24	42	20	48	16	47
Occupational Therapy	2	4	1	2	1	3
Dentist	2	4	1	2	0	0
Medical specialty	**n = 24**		**n = 20**		**n = 16**	
Radiology	8	34	7	35	6	38
Rehabilitation	6	25	5	25	4	25
Otorhinolaryngology	5	21	4	20	3	19
Neurology	2	8	1	5	1	6
Pulmonology	1	4	1	5	1	6
Surgery	1	4	1	5	1	6
Gastroenterology	1	4	1	5	0	0
Highest Qualification	**N = 56**		**N = 42**		**N = 34**	
Doctor of Philosophy	37	66	28	67	22	64
Master's degree (research)	7	12	6	13	4	12
Master's degree (coursework)	6	11	4	10	4	12
Bachelor's degree	6	11	4	10	4	12
Years of experience	**N = 56**		**N = 42**		**N = 34**	
5-10 years	13	23	10	24	9	26
11-15 years	11	20	8	19	7	21
16-21 years	11	20	7	17	5	15
21-30 years	18	32	14	33	11	32
30+ years	3	5	3	7	2	6
***Work sectors**	**N = 77**		**N = 55**		**N = 46**	
University / Education Provider	37	48	26	47	21	46
Health Sector (e.g. hospital)	28	36	19	35	17	37
Private Practice/Small Business	8	10	6	11	4	9
Student (Master's or PhD)	4	5	4	7	4	9
***Caseloads**	**N = 168**		**N = 116**		**N = 71**	
Neurology	38	23	27	23	17	24
Sub-acute care (in-patient rehab.)	28	17	20	17	13	18
Oncology	25	15	17	15	11	15
Acute care (in-patients)	22	13	14	12	10	14
Community care (out-patients)	19	11	12	10	5	7
Tracheostomy	14	8	9	8	5	7

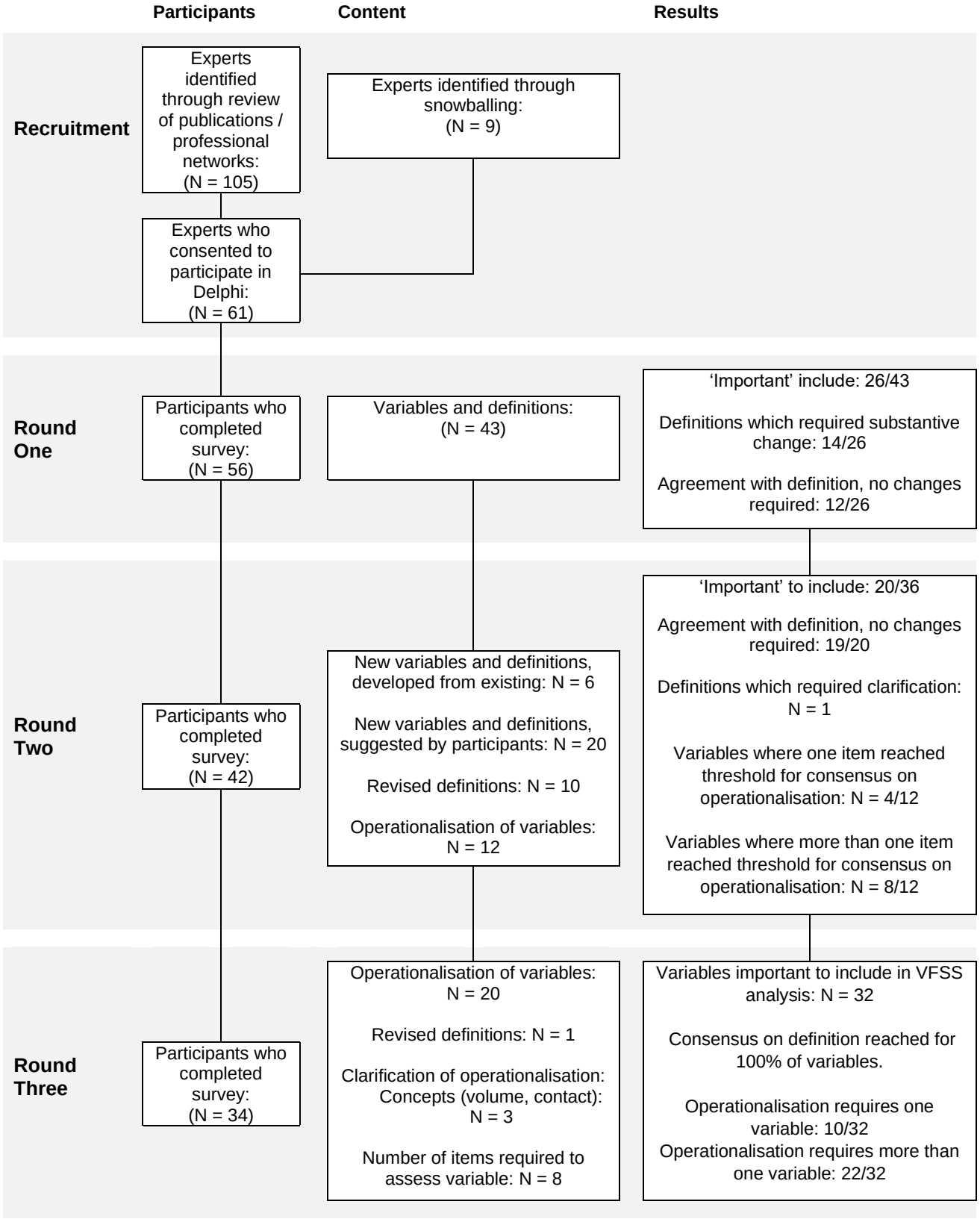
	Round One		Round Two		Round Three	
	Frequency	**Percentage**	**Frequency**	**Percentage**	**Frequency**	**Percentage**
Laryngectomy	10	6	6	5	4	6
Private Practice	6	4	5	4	4	6
Not currently working with caseload requiring VFSS	4	2	4	3	1	1
Residential Aged Care Facility	2	1	2	2	1	1
Participant countries	**N = 27**		**N = 22**		**N = 21**	
Argentina	1	2	1	2	1	3
Australia	4	7	3	7	1	3
Austria	2	4	2	5	1	3
Belgium	2	4	0	0	0	0
Brazil	2	4	2	5	2	6
Canada	1	2	0	0	0	0
China	1	2	1	2	0	0
Denmark	1	2	0	0	0	0
France	3	5	3	7	3	9
Germany	4	7	2	5	2	6
Greece	1	2	1	2	1	3
Hong Kong	2	4	1	2	1	3
India	1	2	1	2	1	3
Italy	3	5	3	7	2	6
Japan	3	5	3	7	2	6
New Zealand	1	2	1	2	1	3
Norway	2	4	2	5	2	6
Poland	1	2	1	2	1	3
Portugal	1	2	1	2	1	3
Slovakia	1	2	1	2	1	3
South Korea	1	2	0	0	0	0
Spain	1	2	1	2	1	3
Sweden	3	5	3	7	3	9
Taiwan	1	2	0	0	0	0
The Netherlands	4	7	3	7	3	9
United Kingdom	2	4	1	2	1	3
United States of America	7	13	5	12	3	9

** Indicates multiple answers permitted*

Process

Results and progression of domains and participants are outlined in Figure 5.

Figure 5: Delphi process



Domains

Across Rounds, a final total of thirty-two domains were recommended to be include in analysis of VFSS. Tables 2 outlines consensus ratings on relevance across all domains, and Table 3 details definitions for the high relevance domains.

Table 2: Relevance to VFSS analysis

Relevance	Round One			Round Two		
Domain	**Percentage**	**Median**	**IQR**	**Percentage**	**Median**	**IQR**
Apraxia of swallowing	62.5%	3	2	-	-	-
Aspiration	100%	1	0	Operationalisation		
Base of tongue to posterior pharyngeal wall approximation	94.6%	1	0.25	Operationalisation		
Bolus formation	92.9%	1	1	Split into new domains: liquid bolus formation and aggregation of solids		
Bolus holding (to command)	64.3%	3	2	-	-	-
Bolus transport	96.4%	2	1	Split into new domains: liquid bolus transport and solid bolus transport		
Clearing swallow (oral)	82.1%	1	1	Operationalisation: of merged single variable: 'clearing swallow'		
Clearing swallow (pharyngeal)	89.3%	1	1			
Cough (reflexive)*	98.2%	1	0	97.7%	1	1
Cough (voluntary)	60.7%	1	2	-	-	-
Delayed swallow*	96.4%	2	0	92.9%	1	1
Epiglottic tilting*	89.3%	2	1	76.2%	1.75	1
Hyoid excursion	100%	1	0	Operationalisation		
Initiation of bolus manipulation	51.8%	3	2	-	-	-
Jaw function	55.4%	3	1	-	-	-
Jaw opening (gape)	32.1%	3	2	-	-	-
Lip closure	66.1%	3	2	-	-	-
Laryngeal close duration / airway close duration	57.1%	3	2	-	-	-
Laryngeal excursion*	96.4%	2	0.25	97.6%	1	1
Laryngeal vestibule closure	89.3%	1	1	Operationalisation		
Lingual motion	89.3%	2	1	Split into new domains: lingual motion (liquids) and lingual motion (solids)		

Glossopalatal seal (liquids)*	82.1%	1	1	78.6%	2	1
Mastication	64.3%	2	2	-	-	-
Nasopharynx penetration	92.9%	1	1		Operationalisation	
Oesophageal redirection	64.8%	3	2	-	-	-
Oesophageal stasis	46.4%	3	1	-	-	-
Oesophageal transit time	51.8%	3	2	-	-	-
Oral residue	94.6%	1	1		Operationalisation	
Oral stasis	62.5%	3	2	-	-	-
Oral transit time	64.8%	2	2	-	-	-
Penetration	100%	1	0		Operationalisation	
Pharyngeal constriction*	83.9%	1	1	92.9%	1	1
Pharyngeal residue	98.2%	1	0		Operationalisation	
Pharyngeal transit time	64.2%	3	2	-	-	-
Piecemeal deglutition*	85.7%	1	1	85.7%	2	1
Posterior oral bolus containment*	82.1%	2	0	81.0%	2	1
Silent aspiration	100%	1	0		Operationalisation	
Total swallow duration	48.2%	3	2	-	-	-
Tracheal residue	80.4%	2	1		Operationalisation	
Upper oesophageal sphincter opening (displacement)*	91.1%	1	0.25	85.7%	1	1
Upper oesophageal sphincter opening (timing)*	94.6%	2	1	97.6%	1	0
Velum elevation	91.1%	1	1		Operationalisation	
Zenker’s diverticulum	70.0%	2	2	-	-	-
Ayrteno-epliglottic approximation	-	-	-	59.5%	2	2
Aggregation of solids	-	-	-	73.8%	2	1
Base of tongue retraction	-	-	-	92.9%	2	1
Discoordination of the Upper Oesophageal Sphincter	-	-	-	78.6%	1.5	1

Expectoration	-	-	-	52.4%	2	1
Lingual incoordination	-	-	-	42.9%	3	1
Lingual motion (liquids)	-	-	-	90.5%	1	1
Lingual motion (solids)	-	-	-	69.0%	2	2
Lip spread	-	-	-	2.4%	3	1
Lip purse (around a straw)	-	-	-	23.8%	3	1
Liquid bolus formation	-	-	-	88.1%	2	1
Liquid bolus transport	-	-	-	95.2%	1	1
Oesophageal transit	-	-	-	64.3%	2	1
Oesophageal residue	-	-	-	64.3%	2	1
Pharyngeal shortening	-	-	-	64.3%	2	2
Pharyngeal wall movement	-	-	-	83.3%	1.5	1
Reflux (pharynx to oral cavity)	-	-	-	54.8%	2	2
Reflux (oesophagus to pharynx)	-	-	-	61.9%	2	2
Thyrohyoid approximation	-	-	-	45.3%	3	1
Residue in valleculae	-	-	-	95.3%	1	0
Residue in pyriform sinuses	-	-	-	97.6%	1	0
Solid bolus transport	-	-	-	83.3%	2	1
Time to laryngeal elevation	-	-	-	50.0%	2.5	2
Throat-clearing	-	-	-	50.0%	2.5	1
Tongue pumping	-	-	-	57.1%	2	2
Velopharyngeal junction closure time in relation to hyoid burst	-	-	-	28.6%	3	1

Key:

** Significant revisions made to definition*

'Operationalisation': progressed to Round Two for operationalisation of concepts (defining variables into measurable factors that can be measured empirically and quantitatively.)

Table 3: Consensus on agreement with definitions for relevant domains

Agreement	Definition†	Percentage	Median	IQR	Round where consensus reached
Aggregation of solids	Triturated* solids aggregate progressively on the base of tongue and in the valleculae. Portions of food may remain in the oral cavity simultaneously while food accumulates in the pharynx (Hiiemae & Palmer, 1999; Palmer, Hiiemae, Matsuo, & Haishima, 2007; Saitoh et al., 2007) **Triturated: chewed and moistened*	83.3%	2	0	2
Aspiration	The bolus or a portion of the bolus passes below the level of the true vocal folds (Frowen, Cotton, & Perry, 2008; Miles et al., 2013; Rosenbek et al., 1996).	96.4%	2	1	1
Base of tongue retraction	Movement of the base of tongue (superior to the epiglottis) towards the posterior pharyngeal wall, as part of the process of pharyngeal constriction behind the tail of the bolus (Veis, Logemann, & Colangelo, 2000).	85.7%	2	1	2
Base of tongue to posterior pharyngeal wall approximation	The base of the tongue moves posteriorly while the posterior pharyngeal wall bulges anteriorly and contact is created between these structures (Frowen et al., 2008; Pauloski & Logemann, 2000).	94.6%	1	1	1
Clearing swallow	An additional swallow initiated in response to the presence of pharyngeal bolus residue (Molfenter & Steele, 2013).	90.1%	2	1	1
Cough (reflexive)	A spontaneous cough in response to aspiration (Steele & Grace-Martin, 2017).	95.2%	1	1	2
Delayed swallow	Delayed swallow:	71.4%	2	2	2*

Agreement	Definition†	Percentage	Median	IQR	Round where consensus reached
	The leading edge of the bolus passes the ramus of the mandible prior to the onset of hyoid burst**. (applies to liquids from a single swallow which was cued - i.e. liquid is held in mouth and swallow is initiated following clinician instruction - only) (Frowen et al., 2008; Martin-Harris, Brodsky, Michel, Lee, & Walters, 2007; Namasivayam-MacDonald, Barbon, & Steele, 2018) ***nb: There is normal variation on the point of swallow onset related to age, which must be represented in the operationalisation of this variable.*				
Discoordination of the Upper Oesophageal Sphincter	Abnormalities in magnitude, onset or duration of upper oesophageal sphincter opening (Eisenhuber et al., 2002; Massey & Shaker, 2006).	83.3%	2	0	2
Epiglottic tilting	The epiglottis tilts over the entrance to the airway, and the arytenoid cartilages move upwards and forwards to contact the laryngeal surface of the downfolding epiglottis (Belafsky & Kuhn, 2014; Kendall, Leonard, & McKenzie, 2004).	90.5%	2	1	2
Glossopalatal seal (liquids)	The velum is lowered to create a seal with the elevated posterior tongue, resulting in a barrier to prevent bolus spillage into the pharynx (Matsuo & Palmer, 2008).	92.9%	2	1	2
Hyoid excursion	The hyoid moves in a superior and anterior direction during hyoid burst (Kim & McCullough, 2008; Steele et al., 2011).	92.9%	2	1	1
Laryngeal excursion	Superior and anterior movement of the larynx (Steele et al., 2011).	85.7%	2	1	2

Agreement	Definition†	Percentage	Median	IQR	Round where consensus reached
Laryngeal vestibule closure	The closure of the laryngeal vestibule during the peak of pharyngeal swallow; when complete, no space is visible between structures (Vose & Humbert, 2018).	89.8%	2	1	1
Lingual motion (liquids)	The tongue elevates progressively from anterior to posterior in the oral cavity, squeezing the bolus along the palate towards the pharynx (Shaker, Belafsky, Postma, & Easterling, 2012).	97.6%	2	1	2
Liquid bolus formation	The bolus is held in the oral cavity on the tongue surface, and may extend to the anterior floor of the mouth. The tongue forms a chamber which shapes the bolus, with contact between the posterior tongue and soft palate (Matsuo & Palmer, 2008).	97.6%	2	1	2
Liquid bolus transport	The bolus is positioned on the surface of the tongue and then squeezed posteriorly into the oropharynx (Matsuo & Palmer, 2008).	90.5%	1.5	1	2
Nasopharynx misdirection	A portion of the bolus enters the nasopharynx (Galluzzi, Schindler, Gaini, & Garavello, 2015).	96.4%	2	1	1
Oral residue	Bolus material which remains in the oral cavity after swallow/s have been completed (J. A. Logemann et al., 2005).	91.1%	2	1	1
Penetration	The bolus or a portion of the bolus enters the laryngeal vestibule but does not pass below the true vocal folds (Frowen et al., 2008; Steele & Grace-Martin, 2017).	75%	2	1	1
Pharyngeal constriction	The available space in the pharynx closes behind the tail of the bolus through a combination of posterior-inferior tongue base movement, superior to inferior contraction of the pharyngeal constrictor muscles and	95.2%	2	1	2

Agreement	Definition†	Percentage	Median	IQR	Round where consensus reached
	shortening of the pharynx via contraction of the longitudinal pharyngeal muscles (which occurs in association with hyolaryngeal elevation) (Jaffer, Ng, Au, & Steele, 2015; Palmer, Tanaka, & Ensrud, 2000).				
Pharyngeal residue	Material that is present in vallecular spaces, pyriform sinuses or elsewhere in the pharynx after a swallow (Jaffer et al., 2015).	75%	2	1	1
Pharyngeal wall movement	The pharyngeal constrictor muscles contract in a superior to inferior sequence, creating a 'wave' of anterior movement that travels down the pharynx behind the tail of the bolus (Jones, 2006).	88.1%	2	1	2
Piecemeal deglutition	The bolus is divided into two or more portions in the mouth and is swallowed in two or more subsequent swallows (Molfenter & Steele, 2013).	92.9%	2	1	2
Posterior oral bolus containment	Liquid is held within the oral cavity without any bolus spillage into the pharynx prior to the elevation of the velum.** (L. Flanagan, 2007)	73.5%	2	1	2
Residue in pyriform sinuses	Any portion of the bolus (more than trace*) that remains in the pyriform sinuses post-swallow (Eisenhuber et al., 2002). **Trace: trace coating in the pyriforms, a line of contrast on the structure*	92.9%	1.5	1	2
Residue in valleculae	Any portion of the bolus (more than trace*) that remains in the valleculae post-swallow (Eisenhuber et al., 2002). **Trace: trace coating in the valleculae, a line of contrast on the structure*	92.9%	1.5	1	2
Silent aspiration	The bolus or a portion of the bolus passes below the level of true vocal folds without resulting in a protective reflexive cough, throat clearing or	85.7%	2	1	1

Agreement	Definition†	Percentage	Median	IQR	Round where consensus reached
	other overt signs that aspiration has occurred (Miles et al., 2013; Ramsey et al., 2005).				
Solid bolus transport	Portions of solid food which have been processed are transported along the tongue, towards the oropharynx. This may occur during chewing cycles (Hiiemae & Palmer, 1999; Palmer et al., 2007; Saitoh et al., 2007).	88.1%	2	1	2
Tracheal residue	Material is present below the true vocal folds, after the pharyngeal swallow has been completed (Eisenhuber et al., 2002).	76.8%	2	1	1
Upper oesophageal sphincter opening (displacement)	Opening of the upper oesophageal sphincter through the action of the hyolaryngeal complex (Kendall & Leonard, 2002)	76.3%	2	1	2
Upper oesophageal sphincter opening (timing)	Opening of the upper oesophageal sphincter is coordinated with the arrival of the bolus at the upper oesophageal sphincter and closely associated with laryngeal elevation, with the laryngeal vestibule closed prior to or synchronously with upper oesophageal sphincter opening. Opening is maintained long enough to allow complete bolus passage (Molfenter & Steele, 2012).	92.9%	1	1	2
Velum elevation	The velum elevates during swallowing to close off the nasopharynx and facilitates passage of the bolus from the oral cavity into the pharynx (Perry, Bae, & Kuehn, 2012).	98.2%	2	1	1

† *Definition: formulated by Delphi Study. Citations: Literature which assisted formulation.*

** progressed to round 3 for clarification of definition due to IQR score outside of accepted range.*

Agreement	Definition†	Percentage	Median	IQR	Round where consensus reached
***applies to liquids from a single swallow which was cued - i.e. liquid is held in mouth and swallow is initiated following clinician instruction – only.*					

Round One

In total, 26 of the 43 domains presented in Round One reached consensus threshold for relevance. Domains rejected at this stage predominantly pertained to processes that participants believed were not suitable to assess with VFSS or not of significant clinical relevance, with participants commenting the following in relation to:

- Apraxia of swallowing:

  'VFSS is not the necessary for making this diagnosis.'

- Lip closure:

  'VFSS is not the best exploration to assess lip closure. For this particular sign, direct clinical observation is much accurate.'

- Jaw function:

  'This cannot be evaluated properly on videofluoroscopy. The evaluation of jaw movement and its coordination with tongue movement requires either movement tracking instrumentation and/or EMG.'

- Mastication:

  'It is inappropriate to assess mastication of food by VFS. It can be assessed by clinical evaluation. It can prolong the radiation time.'

- Oral transit time

  'For clinical purposes the analyzation of bolus transport is much more important than the oral transit time!'

Domains pertaining to the oesophageal phase also failed to reach consensus threshold, with participants again commenting on alternative investigations for these domains:

'Oesophageal High Resolution Manometry combined with impedance is the exploration to assess oesophageal motility and bolus flow.'

'[It's] part of traditional Barium swallow (Esophagogram).'

Consensus scores combined with comments in open-ended questions indicated revisions were required for 14 of the 26 domains judged 'relevant'. Participant comments regarding variables pertaining to the oral phase highlighted the need for oral phase variables to reflect the 'process model' of swallowing for solids (Hiiemae & Palmer, 1999; Palmer, Rudin, Lara, & Crompton, 1992). This led to the formation of novel variables for solids related to the concepts of bolus formation, bolus transport and lingual motion grounded in the process model.

In total, 50 domains were suggested by participants which were categorised according to the property they described - time (e.g., duration of movement) and spatial (e.g., amount of movement, location of issue) variables, diagnoses / anatomical variables (e.g., osteophytes), and when they could be assessed (variables visible at clinical assessment; e.g., patient impulsivity with meals). Suggestions which overlapped revisions to existing domains or definitions were rejected (see Table 4). This resulted in 20 new domains and definitions submitted in Round Two.

Online supplementary Table 4: Participant suggestions – additional variables

	Temporal / spatial	
Progressed to Round Two	• Ayrteno-epliglottic approximation • Base of tongue retraction • Discoordination of the Upper Oesophageal Sphincter • Expectoration • Lingual incoordination • Lip spread • Lip purse (around a straw) • Oesophageal transit • Oesophageal residue • Pharyngeal shortening	• Pharyngeal wall movement • Reflux (pharynx to oral cavity) • Reflux (oesophagus to pharynx) • Thyrohyoid approximation • Residue in valleculae • Residue in pyriform sinuses • Time to laryngeal elevation • Throat-clearing • Tongue pumping • Velopharyngeal junction closure time in relation to hyoid burst
	Diagnoses / anatomical*	

Excluded	• Cervical posture • Cleft palate • Configuration of cardia • Cricopharyngeal bar or fingerprint • Epiglottic swelling • Hyoid / laryngeal / pharyngeal resections • Mucosal changes • Oesophageal calibre • Oesophageal diverticula • Oesophageal hernias Oesophageal polyps	• Oesophageal ring / strictures • Oesophageal tumours • Oesophageal web • Oesophageal tertiary contractions • Osteophytes • Pharyngeal web • Pharyngoceles • Polypoid lesions • Postoperative deformations • Pseudo-zenker's diverticulum • Tracheoesophageal fistula
	Clinical assessment**	
Excluded	• Dental condition • Oral hygiene • Patient mobility • Patient cognition	• Generalised abnormal movements (e.g. Tremors) • Patient behaviour during assessment (alertness, self-feeding behaviours)

Notes: suggestions which were rating scales or items, such as number of swallows per bolus, were excluded from this list. These suggestions were used as item options to rate relevant variables.

**Although authors acknowledge the importance of diagnoses and anatomical abnormalities to management decisions and case formulation, suggestions which pertained to these were not progressed to Round Two. This is intended to reflect the diverse backgrounds of health professionals who interpret VFSS (allied health clinicians as well as medical doctors) and the feedback made by participants, who commented it may be inappropriate for some raters to make medical diagnoses, given this variability in qualifications.*

***Not progressed to Round Two, as may best be assessed outside of the VFSS process.*

Round Two

The majority of definitions of domains which were rated as 'Important' by respondents reached the threshold for consensus agreement with the definition (19/20) in Round Two. One domain, 'delayed swallow' met percentage criteria (71.4%) for agreement with the definition; however, the Interquartile Range did not meet threshold (IQR = 2). The second most common response to this domain was 'Neither agreed nor disagreed' with the proposed definition (19% of participants). Comments indicated a theme of concern regarding the definition's failure to capture normal variability due to age and normal individual variations and indicated the term 'delayed swallow' may commonly be misapplied to normal physiology.

Participants commented:

'…there is much normal variation. If the majority of individuals demonstrate delay, can it be considered "delay"? I encourage assessing bolus location (and dwell time) at onset of initiation of pharyngeal swallow, and avoiding the term delay (that is an impression, not an objective finding on VFSS).'

'It seems appropriate to redefine the definition of Liquid Delayed Swallow.
I propose to describe it not using the anatomical projection of the ramus of the mandible, but rather the time point when the leading edge of the bolus passes the valleculae prior to the onset of hyoid burst. This redefinition includes the age differences in swallowing triggering.'

'We desperately need to avoid clinicians over-analysing normal as disordered.'

'It is difficult to evaluate the definition without knowing the rating scale of this variable. The name 'delayed swallow' does not match the definition as the bolus passing the ramus of the mandible is not a marker of abnormality. I suggest changing the name of the variable to 'swallow triggering' or 'initiation of pharyngeal swallowing 'or something similar.'

'Normal onset can be proven by this observation, but not a pathological one… many patients can voluntarily delay the swallowing action…'

Therefore, the definition for 'delayed swallow' was progressed to Round Three for clarification.

Round Two and Three presented domains for operationalisation of concepts; by the final Round, consensus was reached on at least one item per domain.

Round Three

The domains 'tracheal residue', 'laryngeal vestibule closure' and 'nasopharynx bolus misdirection', failed to reach consensus on items, with an even split between participants selecting all possible items and participants selecting only one item from a choice of two. Authors made the decision to

progress all potential items to the draft measure, to be refined later via the validation process of the new VFSS measure.

As part of operationalisation, participants were asked five additional questions about specific conceptualisation of items where two authors concluded additional detail was required to guide item formulation (e.g., volume as conceptualised in relevance to aspiration). Three items failed to meet the consensus threshold (volume for aspiration, volume for clearing swallow and volume for oral residue). Where this occurred, two authors discussed results and final selection was decided through author consensus, based on the frequency with which items were selected by participants and considerations of which option would be most appropriate for a visuoperceptual measure.

The definition for 'delayed swallow' was re-presented in Round Three, with participants asked to select if they preferred the definition provided in Round Two:

- Delayed swallow: Liquids (single swallow, cued - i.e. swallow following clinician instruction) The leading edge of the bolus passes the ramus of the mandible prior to the onset of hyoid burst.*

  **Hyoid burst: the first superior and/or anterior burst of motion of the hyoid that results in a forward/ upward loop of the hyoid during a swallow.*

However, a revised version was developed:

- Delayed swallow: Liquids (single swallow, cued - i.e. swallow following clinician instruction) The leading edge of the bolus passes the valleculae prior to the onset of hyoid burst.

The original definition was preferred by a narrow margin, with 54% of participants choosing the original definition.

Finally, comments in the open textboxes were analysed by two authors and suggestions for items to be included in the draft measure were enacted where both authors judged they had merit, that is, the suggestions were supported by relevant literature and judged to be 'measurable' for a visuoperceptual measure. This resulted in additional items being added to three variables: 'Discoordination of the Upper Oesophageal Sphincter', 'Solid bolus transport', and 'Upper Oesophageal Sphincter opening (timing)'. Authors also included one additional item in the variable 'pyriform sinus residue' (duration residue remains in pyriform sinuses), despite this variable not

reaching the threshold for multiple items, to maintain consistency with the variable ‘Valleculae residue’.

Table 5: Final consensus: operationalisation of domains

Domain	Consensus: > one item required per Domain: Percent	Items:	Quantification
Aggregation of solids	73.5	**1.** Most inferior location the material reaches prior to the pharyngeal swallow. **2.** Apparent volumes of material aggregating in oral cavity and valleculae immediately prior to the pharyngeal swallow.	- -
Aspiration	N/A 91.2	**Patient response to aspiration** • Success in ejecting material from the airway. **Aspiration:** • Volume of material aspirated. • Aspiration time in relation to the initiation of the pharyngeal swallow (e.g. before / after). • Location of source of aspiration.	- **Volume:** * Estimation of volume below vocal folds using descriptors and / or pictorial references. - -
Base of tongue retraction	52.9	**1.** Degree of movement of the base of tongue towards the posterior pharyngeal wall.	-
Base of tongue to posterior pharyngeal wall approximation	N/A	• Degree of contact between base of tongue and the posterior pharyngeal wall.	○ Dichotomous rating: Contact or Nil Contact.
Clearing swallow	70.6	**Spontaneous and to command** • Location of residue when clearing swallow initiated. • Volume of residue cleared by clearing swallow. • Number of clearing swallows.	Volume: * Estimation of volume remaining using descriptors and / or pictorial references.
Cough (reflexive)	88.2	**1.** Success in ejecting material from the airway. **2.** Latency between material being aspirated and the cough.	- -

Domain	Consensus: > one item required per Domain: Percent	Items:	Quantification
Delayed swallow	76.7	**1.** Location of leading edge of the bolus when swallow initiated. **2.** Latency between bolus passing ramus of mandible and the first motion of hyoid excursion.	- -
Discoordination of the Upper Oesophageal Sphincter	90.9	**1.** Volume of bolus passed through UES prior to UES closure. **2.** Duration of UES opening. **-** Opening in the context of active hyolaryngeal excursion.	- - -
Epiglottic tilting	44.1	**1.** Degree of contact between laryngeal surface of epiglottis and arytenoid cartilages.	-
Glossopalatal seal (liquids)	33.3	**1.** The distance between the lowered velum and elevated tongue prior to initiation of the pharyngeal swallow.	-
Hyoid excursion	47.0	**Hyoid excursion: superior movement** • Distance from resting position to maximal superior position. **Hyoid excursion: anterior movement** • Distance from resting position to maximal anterior position.	- -
Laryngeal excursion	87.9	**1.** Spatial change from resting position to maximal anterior and superior position. **2.** Degree of contact between laryngeal surface of epiglottis and arytenoid cartilages.	- -
Laryngeal vestibule closure	42.4	• Time when arytenoid cartilage to epiglottic base contact occurs in relation to the bolus entry to the pharynx. - Duration of laryngeal vestibule closure.	- -
Lingual motion (liquids)	48.5	**1.** Action of the tongue.	-

Domain	Consensus: > one item required per Domain: Percent	Items:	Quantification
Liquid bolus formation	55.9	**1.** Bolus location during formation.	-
Liquid bolus transport	55.9	**1**. Liquid oral bolus transport in the expected direction.	-
Nasopharynx misdirection	51.5	**1.** Time when material enters the nasopharynx in relation to the pharyngeal swallow. **-** Volume of material which enters the nasopharynx.	- -
Oral residue	73.5	**Oral residue** • Location of residue. • Volume of material which remains.	**Volume:** * Estimation of volume remaining using descriptors and / or pictorial references. -
Penetration	76.5	**Patient response to penetration:** • Success in ejecting material from the supraglottic space. **Penetration** • Permanency /transience of penetration. • Penetration time in relation to the initiation of the pharyngeal swallow (e.g. before / after). • Location of source of penetration.	- - - -
Pharyngeal constriction	72.7	**1.** Contact of base of tongue and velum with lateral and posterior walls of the pharynx. **2.** Presence/absence of any unobliterated space in the pharynx (from C2 to UES) at the moment of maximum constriction (which occurs AFTER bolus entry into the UES).	- -

Domain	Consensus: > one item required per Domain: Percent	Items:	Quantification
Pharyngeal residue	N/A	• Location of residue. • Estimation of volume of material which remains.	- -
Pharyngeal wall movement	60.6	**1.** Visibility of a top-down sequence pharyngeal wall movement following the bolus tail.	-
Piecemeal deglutition	73.5	**1.** Number of portions bolus divided into. **2.** Presence / absence of bolus subdivision in mouth (where bolus volume less than 20cc).	- -
Posterior oral bolus containment	47.1	**1.** Presence of material in pharynx prior to velum elevation.	-
Residue in pyriform sinuses	69.0	**1**. Volume of material which remains. - Duration residue remains in pyriform sinuses.	- -
Residue in valleculae	73.5	**1**. Duration residue remains in valleculae. **2**. Volume of material which remains in valleculae.	- -
Silent aspiration	N/A	• Volume of material aspirated silently. • Time between material being aspirated silently and the initiation of the pharyngeal swallow. • Location of source of aspiration.	- - -
Solid bolus transport	73.5	**1.** Action of tongue. **2.** Posterior movement of the solid bolus. **-** Description of speed of transit.	- - -
Tracheal residue	57.6	**-** Depth of residue below vocal folds. **-** Volume of material which remains.	- -

Domain	Consensus: > one item required per Domain: Percent	Items:	Quantification
Upper oesophageal sphincter opening (displacement)	52.9	**1.** Width of opening.	-
Upper oesophageal sphincter opening (timing)	79.4	**1.** Closure time in relation to volume of bolus passed through upper oesophageal sphincter. **2.** Duration of opening. **-** Timing to glossopalatal juncture opening to upper oesophageal sphincter opening.	- - -
Velum elevation	N/A	• Contact of velum with lateral and posterior walls of the pharynx.	○ Dichotomous rating: Contact or Nil Contact.

Key: Items

- • *Items selected in Round 2. Items reached consensus threshold, but no preference identified (i.e. participants asked to select options which best assessed x variable. Items all selected by >70% of participants).*
- **1, 2** *Items selected in Round 3. Items 'most popular' from total group (i.e. participants were asked to rank items. Where >70% selected two items, most frequently selected items recorded and indicated with relevant numerals (1, 2). Where <70% indicated two items required, most highly ranked item accepted).*
- **-** *Additional items suggested by participants in Round Three, selected by authors following consensus between two authors.*
- N/A *Participants not asked to indicate number of items required to assess variable.*

Key: Quantification

- * *No option reached consensus threshold in Survey. Two authors selected the final quantification option based on participant comments, frequency each item was selected and quantification 'measurability' (i.e. ease of applicability to a visuoperceptual measure).*
- ○ *70% consensus threshold reached for preferred rating scale.*

Discussion

This study established domains and items recommended by experts for the analysis of visuoperceptual measurement of oropharyngeal dysphagia from VFSS recordings. International consensus on definitions for and operationalisation of domains relevant to the construct was reached using the Delphi technique. This study represents new evidence in the field of VFSS research. Even though the VFSS is a recognised gold-standard of some 30 years standing (Logemann, 1993), to date no published study has sought to establish international consensus on measure content.

Participants in this study were recruited from more than twenty countries, representing broad engagement and a wide pool of ideas. Overall, they had a high level of expertise, with most holding PhDs and over 15 years of experience with dysphagia and VFSS. Professionals from all relevant disciplines were included in the study; according to COSMIN guidelines for assessing quality of content validity, this meets the criteria for 'very good' (the highest standard) for soliciting professional's opinions regarding the relevance of measure content. Likewise, according to these criteria the number of professionals who completed all three rounds (>30) is considered 'adequate' (Terwee et al., 2018). Evaluation of the study against these standards, as well as the high level of expertise of participants indicates the overall strength of this study's design and findings.

Models of swallowing

Novel domains formulated through this Delphi study pertained primarily to domains related to solid swallowing and the 'process model' (Hiiemae & Palmer, 1999; Palmer et al., 1992). The 'process model' of swallowing (Hiiemae & Palmer, 1999; Palmer et al., 1992) conceptualises solid swallowing as a series of overlapping processes, rather than the distinct sequential stages of the four-stage model for drinking liquids (Dodds, Stewart, & Logemann, 1990). This difference is important to content formulation, as the 'process model' accounts for the normal food transport and bolus formation in the oro-pharynx seen with solids (Matsuo & Palmer, 2008). In liquid swallowing, the pharyngeal stage normally begins during oral propulsion, as the posterior tongue drops and anterior tongue rises to squeeze the liquid posteriorly along the palate. By contrast, in normal solid swallowing triturated (chewed and moistened with saliva) food normally passes the faucial arches to accumulate in the oropharynx, including valleculae, for several seconds before the pharyngeal phase of the swallow begins. Under the stages model of swallowing, this normal process of solid swallowing would not be

captured or may be inaccurately pathologised. Therefore, the domains content established through this study reflect a contemporary understanding of both normal liquid and solid swallowing.

Definitions

Overall, agreement with definitions was high, with the exception of 'delayed swallow'. Despite this domain's high relevance rating (92.9%), it received low scores on agreement and required three rounds to achieve consensus.

These results might be explained by the 'delayed swallow's' long-standing, but evolving history in VFSS literature. The concept of a 'delayed swallow' is of a similar vintage to the VFSS, and was first described in 1983 as '… the swallow reflex is *not* triggered when the bolus passes the back of the tongue at the anterior faucial arch' (Logemann, 1983, p. 35). A few years later, it was questioned whether this definition was in fact a variation of normal swallowing (Linden, Tippett, Johnston, Siebens, & French, 1989). By 1993, the concept of a 'delayed swallow' had evolved, and was described by Logemann (1993) in her seminal manual on VFSS as follows: 'Normally, when the head of the bolus passes the tongue base (the point where the lower edge of the mandible crosses the tongue base), the pharyngeal swallow should have begun. Delayed pharyngeal swallow occurs when the head of the bolus enters the pharynx and the pharyngeal swallow has not been triggered…' (Logemann, 1993, p. 85).

Although this concept of the radiographic shadow of the ramus of the mandible being the cut-off point for pharyngeal swallow initiation has been repeated in much subsequent literature, clearly there are issues with applying this marker to all texture types; under this definition, normal solid swallowing described by the 'process model' would be considered delayed (Matsuo & Palmer, 2008). Swallowing of mixed consistency boluses (solids and thin liquid components), where the leading edge of the liquid component has been shown to commonly enter the hypopharynx prior to swallowing in healthy young adults (Saitoh et al., 2007) would also be 'delayed'. Similarly, contemporary research has further demonstrated the variability of 'normal' triggering location due to aging (Martin-Harris et al., 2007), sequential swallowing (Daniels et al., 2004), bolus volume (Park et al., 2016), and verbal cues (Daniels, Schroeder, DeGeorge, Corey, & Rosenbek, 2007; Nagy et al., 2013).

Recent work by Steele et al. (2019) establishing reference values for healthy individuals under 60 years of age found a range of normal variability of bolus location at swallow onset with thin fluids, with the bolus located at or above the ramus of mandible only 25% of the time on the frame of

hyoid burst, and bolus equally distributed across deeper locations. Therefore, the definition for delayed swallow that was presented to participants in this study applied to a very specific condition; a single swallow of a liquid to clinician command (verbal cueing). Despite this qualifier, the participants' continued low rating for consensus and comments indicate that this domain must be diagnosed and interpreted with caution. As noted by participants in this study, initiation of the swallow prior to the liquid bolus head reaching the ramus of the mandible may be considered a strong indicator of the absence of impaired swallowing onset, but initiation inferior to this marker cannot necessarily be interpreted as an indicator of presence of impairment. The contention around this domain may indicate a re-conceptualisation of the term 'delayed swallow' is warranted, as the label itself may bias analysis to a conclusion of pathologising normal swallowing function. 'Swallow initiation' may be a more appropriate descriptor.

Domains

From an initial list of 69 domains, 32 were accepted as highly relevant in the first round of the Delphi. Domains that were rejected by respondents generally pertained to lip function, mastication, jaw movements, specific abnormalities of neurology (apraxia of swallowing), and reflux. This finding represents a point of difference from many existing visuoperceptual measures for VFSS, which include one or more of these domains (Bryant et al., 2012; Frowen et al., 2008; Han et al., 2008; Han et al., 2001; Martin-Harris et al., 2008; Scott, 1999; Stoeckli et al., 2003).

Domains pertaining to oesophageal function were also rejected, with participants' comments indicating other procedures, such as high-resolution manometry or esophagrams, were more appropriate to assess oesophageal function. Although this finding is consistent with domain content of most visuoperceptual measures for VFSS retrieved in the 2018 psychometric review (Swan et al., 2018), research by Miles et al. (2015) suggested that the use of the VFSS as an adjunct assessment or screen of oesophageal function for patients referred to VFSS for oropharyngeal dysphagia concerns may have a place in clinical practice. In a study involving 111 patients of mixed aetiologies referred for VFSS for swallowing abnormality, authors included an oesophageal screening process using a large liquid barium bolus and barium capsule. This screen identified 68% of the participants in the study had abnormal oesophageal transit. One third of patients referred to the VFSS clinic presented with solely oesophageal abnormalities, and one third had mixed oropharyngeal and oesophageal abnormalities (Miles et al., 2015).

Miles (2015) suggested that the exclusion of oesophageal review risks incomplete diagnosis and missed opportunities to refer to specialist oesophageal examinations, such as Barium Swallows (Esophagrams). The questions in this Delphi study were not specific to the type of screening described by Miles et al. (2015), as the focus of their study was to develop a diagnostic assessment. Therefore, the place of oesophageal screening cannot be conclusively rejected, and may warrant further research with appropriate instrument development techniques.

Domains which were considered 'important' by nearly all participants (>95% of participants rated as important or essential) were those relating to valleculae, pyriform and pharyngeal residue, aspiration, silent aspiration, penetration, laryngeal excursion, cough (reflex), liquid bolus transport, upper oesophageal opening (timing) and delayed swallow. Across all published visuoperceptual measures of VFSS reviewed by Swan et al. (2018), at least two of these domains appear, with pharyngeal residue being the most commonly used. Penetration and aspiration appear as frequently as swallow reflex initiation and represent the second most common domain (Swan et al., 2018). As this convocation of domains appears frequently in the literature, and likely clinical practice, this result of high acceptance rates is unsurprising.

Only four domains reached 100% consensus on 'importance': penetration, aspiration, silent aspiration and hyoid excursion. Given that aspiration is an essential element in the mix of factors which cause aspiration pneumonia (Rofes, 2018), and the Penetration-Aspiration Scale (Rosenbek et al., 1996), a long-standing measure, well known in the collective conscious, include three of these domains, this result was similarly unsurprising. The result of hyoid excursion achieving 100% relevance, despite its relatively lower prevalence in current VFSS measures (Swan et al., 2018), might be explained by association between hyoid excursion and the domains of aspiration and pharyngeal residue (Steele et al., 2011).

This association was noted in a study by Steele et al. (2011), which examined the correlation between hyoid and laryngeal excursion, and whether movement range was predictive of penetration-aspiration or pharyngeal residue. In a study involving VFSS using thin liquids, authors found participants with hyo-laryngeal anterior displacements of lesser than the first quartile movement range were indeed more likely to present with penetration-aspiration and pharyngeal residue (Steele et al., 2011).

Items and operationalisation

The final round of results identified a total of 32 domains which were deemed relevant and had consensus-achieved definitions for VFSS analysis, with at least one item selected by participants per domain, totalling 60 items overall. The upper range of items included in current measures for VFSS is 23, with an average of seven items (Swan et al., 2018). Although the number of domains and items identified in this study is considerably higher compared to measures identified in Swan et al. (2018), it should be noted that as part of the measure construction and validation process, the initial measure prototype typically has a higher number of domains and items than what is contained in the final measure. This allows for removing of domains and/or items with poor psychometric properties. Therefore, although the results of this study indicate which domains and items experts consider to be important for VFSS analysis, they do not constitute an uncompromising or infallible guide for 'good' VFSS analysis; sound measure validation practices must now establish which of these domains and items truly represent the underlying constructs and can be measured reliably.

With regards to operationalisation, consensus was reached on at least one item per domain in this study. However, specifics of rating scales for items pertaining to volume was not achieved. Current measures for VFSS use a variety of rating scales to describe volume, including ordinal scales with descriptors, percentage estimates and nominal scales (Swan et al., 2018). This result may therefore reflect the range and inconsistency of current visuoperceptual VFSS analysis practices.

Limitations

This study is not without limitations. Although the spread of countries was satisfactory, approximately half of countries involved had just one participant. Even though the purpose of a Delphi study is not to achieve a representative sample, more participants in these countries may have better captured different practices and preferences. Further, although the Delphi technique is an appropriate and well-recognised design for establishing consensus and consulting professionals in content validity, the method used in this study (online, fully anonymous) precluded any opportunities for shared discussion between participants. Authors chose a-priori to keep participants anonymous to remove risk of bias or influence; however, the loss of the potential data pool from public debate must be acknowledged.

Finally, the results from this study indicate domains and items which experts consider to be important for VFSS analysis. These results do not address the important question of whether the domains and items are valid or can they be measured reliably. This Delphi is a first step of instrument development only; trialling of these items in a preliminary measure, which is then analysed and

refined according to both item response theory and classic test theory, is required to claim sound psychometric properties.

Conclusions

Findings from this study suggest that visuoperceptual measures for VFSS must involve a range of domains and items which are grounded in both the stages and processes model for swallowing. Domains which may be assessed clinically, or are better assessed using alternative procedures, are not required in visuoperceptual measurement tools. Many domains may require more than one item to satisfactorily assess the construct of interest. Current measures for VFSS do not meet these recommendations. As a result of this study, a new measure for visuoperceptual VFSS analysis will be developed; the design and quality of this study indicates the content validity for this new measure will be of a high standard.

Acknowledgements

Authors would like to acknowledge and thank the experts who voluntarily participated in all three rounds of the Delphi studies and shared their wealth of knowledge:

Barbara Jamróz

Margareta Bülow

Barbora Bunová

Helena Castro

Pere Clavé

Emmanuelle Cugy

James Curtis

Roberta Goncalves Da Silva

Luka Dagdilelis

Stefano Doratiotto

Olle Ekberg

Lisa Everton

Daniele Farneti

Renata Guedes

Bas Heijnen

Andrea Hofmayer

Mansi Jagtap

Hitoshi Kagaya

Paula Leslie

Bernice Mathisen

Jolanda Meijers

Anna Miles

Walmari Pilz

Dai Pu

Maribeth Rivelsrud

Martina Scharitzer

Catriona Steele

Valéria Tondinelli de Carvalho

Lisa Tuomi

Paivi Tupala

Eric Verin

Tobias Warnecke

Virginie Woisard

Yuki Yoshimatsu

Special acknowledgements:

The authors wish to gratefully acknowledge Catriona Steele, for her generous contribution of her times and expertise in revising and formulating items and definitions for domains.

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